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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,831	02/16/2001	Mikael Forsberg	10806-60A	3598

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EXAMINER

SIPOS, JOHN

ART UNIT PAPER NUMBER

3721

DATE MAILED: 10/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/785,831

Applicant(s)

FORSBERG ET AL.

Examiner

John Sipos

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/20/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-27 and 103-124 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-27 and 103-124 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/02/03 has been entered.

REJECTION ON PRIOR ART

Claims 21-27 and 103-124 are rejected under **35 U.S.C. ' 103(a)** as being unpatentable over the patent to Hjertman (5,435,076) in view Galy (5,148,450) or Meyer (4,491,876). The patent to Hjertman discloses the method of forming an ampoule by inserting a first piston 3 into the front chamber 5 of the barrel, filling the front chamber with a solution, performing a lyophilizing step, sealing the front opening of the barrel by inserting a sealer 11 into the opening, connecting and securing the sealer with the sleeve, filling the second chamber with material 6 and inserting a second piston 25 into the barrel. The patent does not disclose how the first piston is inserted into the barrel.

Since Hjertman teaches the use of a constant diameter barrel and since the barrel is empty at the time of insertion of the piston, there are only two options for inserting the piston, i.e. through the front end or through the rear end. It would have been obvious to one of ordinary skilled in the art to eliminate the turning over steps of the ampoule and perform as many steps as possible from the same end of the ampoule by inserting both the filling material and the piston through the same front end.

To further support this modification, the patents to Galy and Meyer are cited to show the insertion of a piston/movable plug 9 and 25, respectively, and the filling material through the same end of the ampoule since the diameter of the ampoules is constant. It would have been obvious to one of ordinary skilled in the art to insert the piston and material of Hjertman through the same front opening as shown by the secondary references since the diameter of the Hjertman piston is the same as the diameter of the ampoule.

RESPONSE TO APPLICANT'S ARGUMENTS

Applicant's arguments with respect to the claims have been considered but are not persuasive.

The patent to Hjertman shows in Figure 3 an ampoule in which the barrel has a constant diameter that is the same as the diameter of the piston 3. Applicants argue that this figure is "the general shape depicted in Figure 2" of Hjertman and that "any barrel features of Fig. 2 which are omitted from Fig. 3 are impliedly included to permit the cartridge to function in a manner consistent with the remaining teaching of Hjertman". The Examiner maintains that Figure 3 of Hjertman represents a different embodiment with structures that are clearly shown in the figure to be different than the equivalent structures shown in Figure 2. The Hjertman cartridges would operate and function in the same manner with either design. Hjertman clearly states that Figure 3 is a modification (see column 3, line 8-11 and column 4, lines 25 and 26) and Figure 3 clearly shows a constant diameter barrel different from the varying diameter barrel of Figure 2. In view of

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this clear depiction it cannot be argued that Figure 3 doesn't show a constant diameter barrel.

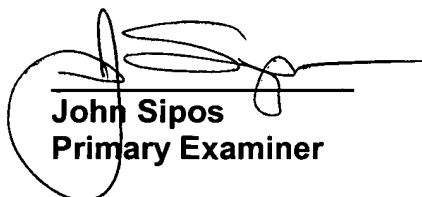
Applicants further argue that the secondary references do not teach the claimed process. These references were cited and applied against the claims to merely show the well-known steps of filling an ampoule and inserting a piston through the same end of the ampoule. Although the Examiner maintains, as stated in the rejection, that the claimed process is an obvious modification of the Hjertman process even without the secondary references, the patents to Galy and Meyer were used to further show that the same end insertion of the piston and the filling material is well known in the art.

Any inquiry concerning this communication should be directed to **Examiner John Sipos** at telephone number **(703) 308-1882**. The examiner can normally be reached from 6:30 AM to 4:00 PM Monday through Thursday.

The **FAX** number for Group 3700 of the Patent and Trademark Office is **(703) 305-3579**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Rinaldi Rada, can be reached at (703) 308-2187.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Receptionist whose telephone number is (703) 308-1148.



John Sipos
Primary Examiner